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Yasuyoshi Ueda

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EXAMINER

BARHAM, BETHANY P

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,669	<b>Applicant(s)</b> UEDA ET AL.	
	<b>Examiner</b> BETHANY BARHAM	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 21-24, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

Receipt of Applicants response and claim amendments filed on 04/27/10 are acknowledged. Claims 1-24 and 29-30 are pending and claims 1-14, and 17-20 remain withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claims 15, 16, 21-24 and 29-30 are examined on the merits.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/27/10 has been entered.

## **MAINTAINED REJECTIONS**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15, 23-24 and 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Chopra (US 6,441,050).

The instant claims are drawn to a process for producing a ubiquinol-enriched oil/fat-containing food product for human ingestion which comprises dissolving ubiquinol in oil/fat under heating, cooling an obtained solution to give a homogeneous oil/fat composition and manufacturing the ubiquinol-enriched oil/fat-containing food product using the composition wherein the oil/fat has a melting point of not lower than 20°C and the homogeneous oil/fat composition is obtained by cooling the obtained solution thereby solidifying the composition or cooling the obtained solution and kneading it thereby plasticizing the composition.

- Chopra teaches an oral palatable food composition in liquid form (i.e. beverage) comprising a mixture of ubiquinol and ubiquinone together with polysorbate and/or sorbitan fatty acid ester (Span<sup>TM</sup>) emulsifiers, lecithin, triglycerides/oil (such as tallow, lard, etc (which are solid oils at room temperature; see cited as interest below)) and a sweetener (i.e. ordinary human food/confection) (abstract, col. 8, lines 5-14; col. 3, line 45-col. 4, line 67, claim 1). According to the instant specification (PGpub, [0092]) emulsifiers include sorbitan fatty acid esters and lecithin, thus meeting the limitations of instant claims 15 and 24.
- The emulsifiers polysorbate and Span<sup>TM</sup> are present from 0.1-35%, preferably 1.5-25% and the triglyceride/oil component which includes hydrogenated vegetable oils, tallow, lard, stearin, etc present from 0.2-50% which reads on the

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oil/fat content of not less than 0.5% (abstract, claim 1) (meeting the limitations of instant claims 23).

- The ubiquinol is added to the oil/fat then heated and lastly added to the sweetener (col. 9 lines 45-55; col. 11, lines) (according to the limitations of instant claims 15 and 25).
- Chopra teaches that the composition is removed from heat and mixed while cooled (col. 11, lines 51-54) (meeting the limitations of instant claim 28).
- The formulation is preferably a ubiquinol-oil emulsion according to Chopra (col. 5, lines 48-55; col. 7, lines 13-15) (meeting the limitations of instant claim 29).
- A syrup product is taught in Example 1 (meeting the limitations of instant claim 30).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 16, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (US 6,441,050).

- Chopra is taught above and teaches an oral palatable food composition in liquid form (i.e. beverage) comprising a mixture of ubiquinol and ubiquinone together

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with an emulsifier, oil such as lard and a sweetener (i.e. ordinary human food/confection).

- Chopra further teaches that the ubiquinone is converted into ubiquinol by the addition of a reducing agent. See e.g. col. 10 lines 14-20.
- Chopra teaches coenzyme Q (ubiquinone) or ubiquinol ranging from about 0.5% to about 10% by weight of the composition, the amount of ubiquinol is 0.1 to 10 times the amount of the reducing agent and that the ubiquinone/ubiquinol amount is about 0.1- about 10% by weight of the final composition (abstract, col. 3, lines 25-30). The ratio of ubiquinol/ubiquinone (instant claim 21) is not explicitly mentioned, nor is the percent of the composition as ubiquinone (instant claim 22), however, given that the ubiquinone is converted to ubiquinol, it is the Examiners opinion that the ubiquinone will be less than 50% by weight after conversion, and specifically between the range of 0.0001 to 50% of instant claims 21 and 22.
- Regarding claim 16, the purity of ubiquinol is not explicitly mentioned in the reference; however, a purity of greater than 0.01% is a large range it is the Examiner's opinion that would cover the ubiquinol used in Chopra. Furthermore, the large range claimed demonstrates that a specific purity is not of significance and it is believed that anytime a reference specifically mentions "ubiquinol" the purity will far exceed 0.01%, especially after conversion of ubiquinone to ubiquinol as taught by Chopra.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make a process for producing ubiquinol-enriched oil/fat containing foods comprising adding the ubiquinol and ubiquinone together with an oil/fat containing food to a sweetener/food material at elevated temperature, as taught by Chopra. There is motivation to have ubiquinone in a lower ratio or proportion because Chopra teaches converting a portion of ubiquinone to ubiquinol. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

#### **Cited As Interest**

Lard definition from Wikipedia (<http://en.wikipedia.org/wiki/Lard>) has a melting point of 30-48 degrees C depending on the area of the pig that it is that it is from (i.e. backfat is 30-40 degrees C) (pg. 2).

Span 60 has a melting point of 54-57°C according to the product information sheet (<http://www.chemblink.com/products/1338-41-6.htm>).

#### ***Response to Arguments***

Applicant's arguments with respect to claims 15-16, 21-24 and newly added claims 29-30 have been considered but are not persuasive. Applicant's argue that the amendment to the claims overcomes the prior art, however the amendment to recite "thereby solidifying the composition" and "thereby plasticizing the composition" does not

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further limit the process steps of instant claim 15. The Examiner respectfully points out that the instant claim 15 only requires steps of i) dissolving ubiquinol in oil/fat (MP of not lower than 20 degrees C) under heating, ii) cooling the solution/composition, and iii) manufacturing the ubiquinol enriched oil/fat containing food product which the prior art teaches. The Examiner suggests an amendment to make the claims allowable, if the Applicants were to amend the instant claim 15 to contain a step of ii) "...cooling an obtained solution by quenching to 20°C or below to give a homogeneous oil/fat composition..." (instant specification page 23, lines 33-34). Such an amendment to include a quenching temperature of 20°C or below would overcome the prior art which only teaches cooling to 100°C while mixing (Chopra col. 11, lines 51-53) and result in allowable subject matter.

Applicant argues that composition of Chopra is not homogeneous. The Examiner respectfully disagrees as the Example of Chopra teaches that upon heating and stirring a clear solution is obtained (or uniform consistency) (such as syrup in Example 1 and col. 9, lines 51-52), and since the process/composition of the prior art are the same as instant claimed the product formed would naturally be homogenous.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BETHANY BARHAM whose telephone number is (571)272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/B. B./  
Examiner, Art Unit 1615

/S. TRAN/  
Primary Examiner, Art Unit 1615